IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

E. CLAIBORNE ROBINS COMPANY, INC.,	)	
Plaintiff	)	
v.	)	
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
and	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
and	)	**Civil Action No: 3:18-cv-827**
TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	
and	)	
CEPHALON, INC.,	)	
Defendants.	)	

SECOND AMENDED COMPLAINT

COMES NOW Plaintiff E. Claiborne Robins Company, Inc. ("Robins"), by counsel, and for its Second Amended Complaint states as follows:

Introduction

1. This contract dispute arises out of Defendants' failure to perform their obligations under an Asset Purchase Agreement ("Agreement") dated August 23, 2007. A copy of the Agreement is attached hereto as **Exhibit 1**.

2. In the Agreement, Robins sold its rights in the drug "Amrix"—a patented extended-release form of cyclobenzaprine hydrochloride—to Anesta A.G. ("Anesta"), a Swiss pharmaceutical company later acquired by Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.").

3. In addition to making an initial payment, Anesta agreed to certain earnout payments whose amounts hinged on Amrix's sales during the earnout period.

4. To protect Robins' rights to those earnout payments, the Agreement requires Anesta and Anesta's affiliates and successors to use "Commercially Reasonable Efforts"—a term defined in the Agreement—to market and sell the drug.

5. Under the Agreement, the failure to use Commercially Reasonable Efforts triggers an alternate formula for Robins' post-sale compensation.

6. Anesta, its affiliates, and its successors have failed to use "Commercially Reasonable Efforts" in their marketing of Amrix, thereby triggering the Agreement's alternate formula for post-sale compensation.

7. Under that formula, Defendants must pay Robins $97.5 million, plus pre-judgment interest, as additional consideration for the rights to Amrix.

8. Defendants have refused to pay that amount, giving rise to the present contract action.

Parties, Jurisdiction, and Venue

9. Plaintiff Robins is a Virginia corporation with its principal place of business in Richmond, Virginia.

10. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), is an Israeli corporation having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

11. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales PA 19454. It is a wholly owned subsidiary of Teva Ltd.

12. Defendant Cephalon, Inc. ("Cephalon"), is a Delaware corporation having its principal place of business at 41 Moores Road, Frazer, PA 19355. It is a wholly owned subsidiary of Teva Ltd.

13. Anesta AG ("Anesta") was a Swiss corporation having its principal place of business at Baarerstrasse 23, CH-6300 Zug, Switzerland. It was a wholly owned subsidiary of Teva Ltd.

14. In 2012, Anesta merged with Ivax International GmbH ("Ivax"), a wholly owned subsidiary of Teva Ltd.

15. Ivax later changed its name to Teva Pharmaceuticals International, GmbH ("Teva Int'l").

16. Defendant Teva Int'l is a Swiss corporation having its principal place of business at Alpenstrasse 2, 8640 Rapperswil, Switzerland. It remains a wholly owned subsidiary of Teva Ltd.

17. The Agreement between Robins and Anesta was made in—and closed in—Richmond, Virginia. It has been performed in significant part in Richmond, Virginia.

18. Section 13.11 of the Agreement provides that the parties irrevocably submit to jurisdiction and venue in the City of Richmond, Virginia, for any action arising out of the Agreement.

19. Pursuant to § 13.07, all of Anesta's obligations under the Agreement—including the consent to personal jurisdiction and venue contained in § 13.11—are "binding upon…the parties hereto and their respective successors and permitted assigns."

20. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs; and there is complete diversity.

The Drug

21. Robins developed and owned a patented extended-released form of cyclobenzaprine hydrochloride, sold under the trade name Amrix.

22. Cyclobenzaprine hydrochloride, a muscle relaxant, has long been available in an immediate-release formulation.

23. The immediate-release formulation, however, needs to be taken multiple times a day. As a result, patient compliance suffers.

24. The need for an extended-release form of cyclobenzaprine hydrochloride was clear, but an extended-release form had not been successfully developed.

25. Robins saw the market need for an extended-release form of cyclobenzaprine hydrochloride and developed patented methods for creating an extended-release version of the drug.

26. Amrix only needs to be taken once a day, improving patient compliance and patient outcomes.

Robins Sells Anesta the Rights to Amrix

27. Amrix was approved by the U.S. Food and Drug Administration under New Drug Application 21-777 effective February 1, 2007.

28. In August 2007 Anesta and Robins entered into the Agreement, pursuant to which Robins sold to Anesta all of Robins' rights and obligations related to Amrix.

29. The Agreement required Anesta to pay Robins a "Base Purchase Price." But it also included a twelve-year earnout provision, entitling Robins to up to $255 million if Amrix sales met certain "Net Sales Milestones."

30. The Net Sales Milestone Termination Date – i.e., the end of the earnout period was August 28, 2019.

31. Robins recognized that the business position and strategy of Anesta—and any of Anesta's "Affiliates"[1] or "Successor Entities"[2]—could change during the twelve-year earnout period, such that it might make economic sense to sacrifice Amrix sales to focus on other products.

32. The Agreement, however, gave Robins no direct control over the sales and marketing efforts made for Amrix during the earnout period.

33. To assure Robins that it would not sacrifice Amrix sales in this way, Anesta agreed that Anesta, its Affiliates, and any Successor Entity, would at all times during the earnout period use "Commercially Reasonable Efforts" to market and sell Amrix.

34. Section 4.02(c) of the Agreement defines "Commercially Reasonable Efforts" as "the efforts and resources that would be used (including the promptness in which such efforts and resources would be applied) by [any person] consistent with its normal business practices."

35. Continuing, § 4.02(c) states that Commercially Reasonable Efforts "in no event shall be less than the ***level of efforts and resources standard in the pharmaceutical industry for a company similar in size and scope*** to such Person, with respect to a product at a similar stage in its development or product life." (Emphasis added).

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[1] The Agreement defines "Affiliate" for this requirement as an entity that, directly or indirectly, controls, is controlled by, or is under common control with Anesta. § 1.01(b).

[2] The Agreement defines "Successor Entity" as "a successor entity to Buyer following a Change of Control." A "Change of Control" is defined as a transaction in which Cephalon, Inc.'s voting power ceased to represent 50% or more of the surviving entity. § 1.01(f).

36. In evaluating whether Anesta, its Affiliates, or any Successor Entity, has complied with the obligation to use Commercially Reasonable Efforts to market and sell Amrix, the parties are to consider "efficacy, safety, commercial value, the competitiveness of alternative products of third parties that are in the marketplace or under development, and the Patent and other proprietary position of such products." Agreement § 4.02(c).

37. Notably, these considerations do *not* include: (1) the obligor's overall financial state, (2) the mix of drugs within the obligor's portfolio, including drugs with similar indications, or (3) whether it would be more profitable for obligor to shift its marketing and sales efforts from Amrix to other products.

38. Section § 4.02(c) of the Agreement instead imposes an objective standard on the obligor's marketing and sales efforts, requiring the "level of efforts and resources standard in the pharmaceutical industry for a company similar in size and scope" to Anesta and Cephalon.[3]

39. The Agreement states that if "at any time" during the twelve-year earnout period, Anesta, its Affiliates, or any Successor Entity failed to undertake Commercially Reasonable Efforts, a separate compensation provision would be triggered. Agreement § 4.02(c).

[3] Section 4.02(c) of the Agreement states that "[T]he 'Commercially Reasonable Efforts' to be used by Buyer under this Section 4.02(c) shall not be less than those efforts Parent [i.e., Cephalon] would be obligated to take under this Section 4.02(c) if Parent had executed and delivered this Agreement as Buyer."

40. Once that provision is triggered, Robins becomes entitled to "an amount equal to 50% of (A) $255 million less (B) the aggregate amount of all Net Sales Milestone Payments made to Seller." Agreement § 4.02(c). Because this is in effect a recalculation of the purchase price, there is no requirement for Robins to prove proximate cause or damages.

41. Defendant Cephalon guaranteed Anesta's performance of its duties under the Agreement. A copy of the Guaranty, executed by Cephalon in August 2007, is attached hereto as **Exhibit 2**.

Teva Acquires Anesta and Cephalon

42. At the time of the 2007 Agreement, Anesta was a wholly owned subsidiary of Cephalon.

43. In 2011, Teva Ltd.—the world's largest seller of generic drugs—purchased Cephalon for $6.8 billion. After the transaction, Cephalon became a wholly owned subsidiary of Teva Ltd.

44. In 2012, Anesta merged with another wholly owned subsidiary of Teva Ltd., Ivax International GmbH ("Ivax").[4]

45. As a result of the merger, Ivax assumed Anesta's rights and obligations under the Agreement.

46. Ivax later changed its name to "Teva Pharmaceuticals International GmbH" ("Teva Int'l").

[4] In December 2012, "Anesta AG" was deleted from the Swiss Commercial Register.

47. Since 2011, Robins' communications about Amrix have been with Teva USA, Teva Ltd., or Teva Int'l (collectively, "Teva"). They have not been with Cephalon or Anesta.

48. Teva has been vague about which entities within the Teva umbrella of companies have assumed or have been assigned rights and obligations under the Agreement.

49. During the present litigation, too, Teva has been vague about which Teva entities have rights or obligations under the Agreement.

50. Teva Ltd. and Teva USA have faulted Robins for not alleging any facts about the assignment of rights and obligations vis-a-vis Amrix within the Teva family of companies.

51. Yet Teva Ltd. and Teva USA have not informed Robins or the Court as to which Teva entity or entities, if any, have assumed or been assigned rights under the Agreement.

52. Robins does not know, and has no way of knowing, about transactions concerning Amrix that have occurred within the Teva family of companies.

53. On information and belief, Teva Ltd. has caused Anesta, Cephalon, and/or Teva Int'l to assign, license, or transfer rights and obligations vis-à-vis Amrix to other entities under the Teva Ltd. family of companies, including Cephalon, Teva USA, Teva Int'l, and Teva Ltd.

54. "As successors and permitted assigns," Cephalon, Teva USA, Teva Int'l, and Teva Ltd. are bound by the Agreement, including the earnout payment obligations set forth in § 4.02(c).

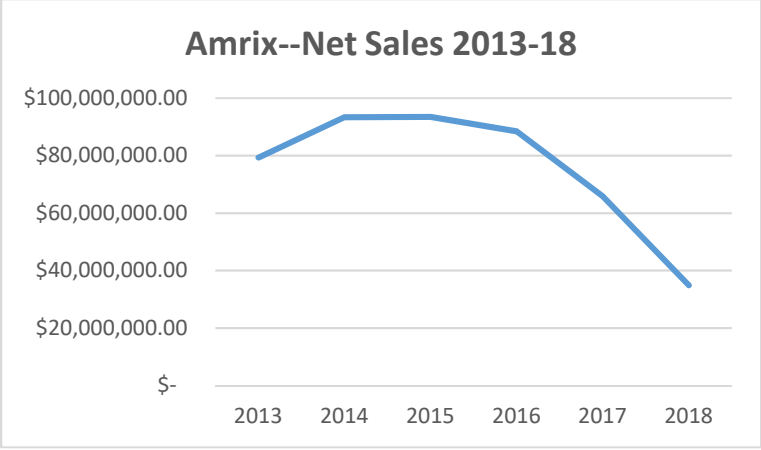
55. Under the Guaranty, Cephalon and its successors and assigns, if any, have guaranteed the performance of the earnout payment obligations set forth in § 4.02(c).

Amrix Sales Drop Precipitously

56. During the initial years following Teva Ltd.'s acquisition of Cephalon, Net sales of Amrix were robust.

57. Starting in 2016, however, Amrix's net sales have dropped precipitously.

58. Net sales of Amrix between 2013 and 2018 are summarized in the following chart:



59. There was nothing about Amrix itself to explain this precipitous drop that began sometime in 2016.

60. Amrix has been shown to be safe and effective, and there are no published during the relevant period (i.e., 2014 to 2019) and were no studies during the relevant period calling into question Amrix's safety and efficacy.

61. Nor was there any drop in Amrix's commercial value or competitiveness. It remains under patent and is the only extended-release form of cyclobenzaprine hydrochloride on the market.

62. There are no lower-cost substitutes that are safer and more effective than Amrix.

63. There were no changes in the patent status of competing drugs that could account for the drastic decline in sales that Amrix experienced after 2015.

64. In short, there was nothing about Amrix or market conditions during this period to explain the precipitous decline in Amrix's net sales.

65. Nor was there anything about Amrix or market conditions during this period that would justify Defendants in cutting marketing efforts for Amrix.

66. Because there was nothing about Amrix or market conditions that explained the decline in Amrix sales, Robins began to suspect that the decline was due to Defendants' failure to undertake Commercially Reasonable Efforts to market and sell Amrix.

Teva Ltd.'s Financial Setbacks

67. These suspicions were buttressed by Robins' learning about a series of financial setbacks that Teva Ltd. suffered during that period.

68. Among other things, Teva Ltd. has had to pay $1.2 billion to settle an antitrust claim brought by the Federal Trade Commission for Teva's allegedly paying a competitor to belay bringing to market a drug that would have competed with one of Teva's drugs.

69. Teva Ltd. also undertook significant debt. In August 2016, Teva Ltd. paid $40 billion to acquire Allergan PLC's generic drug business ("Actavis"), incurring $33.75 billion in debt and concomitant debt-service obligations.

70. In December 2016, Teva Ltd. paid the U.S. Government another fine of $519 million for having violated the Foreign Corrupt Practices Act.

71. Due to these heavy drains on Teva Ltd.'s funds and other poor decisions, the market capitalization of Teva Ltd.'s stock fell from $59.78 billion dollars as of January 5, 2016 to $12.02 billion as of November 8, 2017, a drop of $47.7 billion or 79.89%.

Defendants Stop Undertaking Commercially Reasonable Efforts to Market Amrix

72. In light of its crushing debt and its stock price's tailspin, Teva Ltd. and Teva USA took drastic measures to cut costs.

73. Teva Ltd. and Teva USA slashed billions of dollars of costs across the board, including for marketing and sales.

74. As a result of Teva Ltd.'s poor financial position, Defendants stopped undertaking Commercially Reasonable Efforts to market and sell Amrix.

75. Teva's straitened financial position has caused Defendants to sacrifice Amrix—shifting its marketing efforts to other products.

76. To verify this fact, Robins has repeatedly tried to obtain information from Defendants about the nature and magnitude of marketing efforts that Defendants were undertaking on Amrix's behalf.

Teva Stonewalls Robins

77. In the past, Defendants had been relatively forthcoming with information concerning its marketing and sales efforts for Amrix.

78. For example, in 2012 Teva promised Robins it would have 325 sales representatives pushing the sale of Amrix. This is the number of sales representatives required to satisfy Commercially Reasonable Efforts under the Agreement.

79. In a May 19, 2014 email from Teva to Robins, attached hereto as **Exhibit 3**, Teva stated that "there are 324 sales representatives selling Amrix" and that Teva's marketing efforts and marketing budget for Amrix remained constant between 2013 and 2014.

80. From 2015 onward, however, Teva has refused to provide any meaningful information about its marketing efforts and marketing budget for Amrix.

81. For example, in a November 28, 2017 email from Robins to Teva, attached hereto as **Exhibit 4**, Robins states that "Upon receiving the most recent Q3 Net Sales/Royalty statement for Amrix, it is clear that their [sic] has been a drastic change in the marketing of the Amrix product."

82. Continuing, the email states that "I have requested additional information on the changes in marketing and accounting changes [sic] (Nov 7) and have not gotten a response."

83. The Teva representative refused to have a telephone conversation about the matter. Although Robins repeatedly had requested specific information on recent marketing changes, Teva provided only vague and inadequate excuses for Amrix's dramatic decline in sales

84. Unlike its explanation in 2014 (Exhibit 3), Teva refused to state how many sales representatives were marketing Amrix, how much money Teva was spending on other efforts to market Amrix, or how Teva's marketing efforts compared to prior years.

85. Teva told Robins that there are generic formulations of muscle relaxants on the market that managed care organizations prefer.

86. The market, however, was highly genericized at the time Robins developed Amrix. So this did not explain the recent decline in Amrix sales.

87. Teva also said that it was no longer offering copay coupons, a marketing component recognized in the industry as critical to successful sales efforts for brand name prescription drugs like Amrix, but failed to explain why.

88. Teva's responses to Robins' request for information seemed to verify Robins' concerns that Teva no longer was undertaking Commercially Reasonable Efforts to market and sell Amrix.

89. On January 9, 2018, E. Claiborne Robins Jr.—Robins' President and CEO—wrote to Teva, stating that Teva's excuses for Amrix's precipitous sales decline were inadequate. A copy of this letter is attached hereto as **Exhibit 5**.

90. Mr. Robins noted that "[w]e have not received prompt or detailed information from Teva regarding its [sales and marketing efforts]"—a fact that he said Robins found "disconcerting."

91. Mr. Robins also said that he believed Teva was not undertaking "Commercially Reasonable Efforts" to sell and market Amrix.

92. Therefore, Mr. Robins asked "to discuss in detail Teva's belief that it has acted in a commercially reasonable manner."

93. Continuing, the letter states that "[t]his dialogue needs to be at the appropriate level at Teva given the substantial damage potential."

94. Mr. Robins warned that the matter "requires significantly more information than what has been provided to [Robins] in the past."

95. Teva refused to accept Robins' suggestion that the parties have a discussion about marketing efforts rather than just trade emails and letters.

96. Teva continued to blame Amrix's poor performance on the genericization of the market (an explanation which—as noted above—does not explain the sharp dropoff in Amrix sales from 2016 onward).

97. Teva claimed that the coupon program was "unsustainable," but failed to explain what new events or circumstances had made it so.

98. Because of Teva's stonewalling, Robins has been unable to obtain any concrete information about what Amrix-related marketing and sales efforts, if any, Defendants have undertaken in the last few years

99. Robins has no choice but to depend on Teva for this information. It has no independent way of obtaining those facts.

100. Defendants, in turn, have a strong incentive to conceal facts showing inadequate marketing and sales efforts for Amrix: if they disclose that they have failed to use Commercially Reasonable Efforts, they will have to pay Robins more than $100 million under the alternate payment provisions of § 4.02(c).

101. Teva's vague and inadequate answers, its stonewalling, and its refusal to engage in any discussion with Robins about marketing and sales efforts for Amrix strongly suggest that Defendants are trying to conceal information showing inadequate marketing and sales efforts for Amrix.

102. In light of these circumstances, Robins alleges that Defendants stopped using Commercially Reasonable Efforts sometime in 2016.

103. Defendants improperly cut their marketing efforts for Amrix in several ways, including but not limited to, the following:

- **Sales force.** The minimum sales force to meet Commercially Reasonable Efforts was 325. They cut that number substantially and unreasonably.
- **Co-pay card program.** The co-pay card program was an essential component of Commercially Reasonable Efforts. They cut that program substantially and unreasonably.
- **The discount coupon program.** The discount coupon program was an essential component of Commercially

> Reasonable Efforts. They cut that program substantially and unreasonably.

104. Teva's slashing of its marketing and sales efforts for Amrix are not justified by considerations of efficacy, safety, commercial value, the competitiveness of alternative products of third parties that are in the marketplace or under development, or the Patent and other proprietary position of Amrix.

105. Taking all of these factors into account, a company similar in size and scope to Cephalon, Teva USA, or Teva Ltd. would not have made the same reductions in sales force, marketing budget, and marketing efforts made by Teva.

106. Accordingly, at some point during the 12-year earnout period, beginning in 2016 or shortly thereafter, Defendants ceased using "Commercially Reasonable Efforts," as that term is defined in § 4.02(c) of the Agreement, with respect to the marketing and sale of Amrix.

107. Defendants' failure to use Commercially Reasonable Efforts at all times with respect to the marketing and sale of Amrix triggered the obligation set forth in Section 4.02(c) for Defendants' to pay Robins compensation determined by contract formula—50% of $255 million less the aggregate amount of all Net Sales Milestone Payments to date.

108. The Net Sales Milestone Payments to date are $60 million. Thus, Teva Ltd. and Teva USA owe Robins $97.5 million in accordance with Section 4.02(c) of the Agreement (50% of the difference between $255 million and $60 million), which they have failed and refused to pay Robins.

109. Teva Ltd. and Teva USA also owe Robins pre-judgment interest on this amount from the day that Teva Ltd. and Teva USA first failed to use Commercially Reasonable Efforts with respect to the marketing and sale of Amrix, which interest is expected to bring the total owed by Teva Ltd. and Teva USA to Robins to at least $110 million.

110. Section 13.12(b) of the Agreement authorizes the award of out-of-pocket costs and attorney's fees to the prevailing party in an action to enforce the terms of the Agreement.

WHEREFORE, Plaintiff E. Claiborne Robins Company, Inc., demands judgment against Defendants, jointly and severally, in the amount of at least $110 million. Pursuant to Section 13.01 of the Agreement, Plaintiff prays further for an award of attorney's fees and other out-of-pocket costs incurred in connection with this action.

PLAINTIFF DEMANDS TRIAL BY JURY ON ALL ISSUES SO TRIABLE.

Dated: October 10, 2018

Respectfully submitted,

E. CLAIBORNE ROBINS COMPANY, INC.

By: /s/ Thomas M. Wolf
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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of October, 2019, I will electronically file the foregoing Second Amended Complaint using the CM/ECF system, which will then send a notification of such filing to counsel for Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. Teva Pharmaceuticals International GMBH, and Cephalon, Inc. will be served copies of the Summons and Second Amended Complaint in accordance with the Federal Rule of Civil Procedure 4.

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